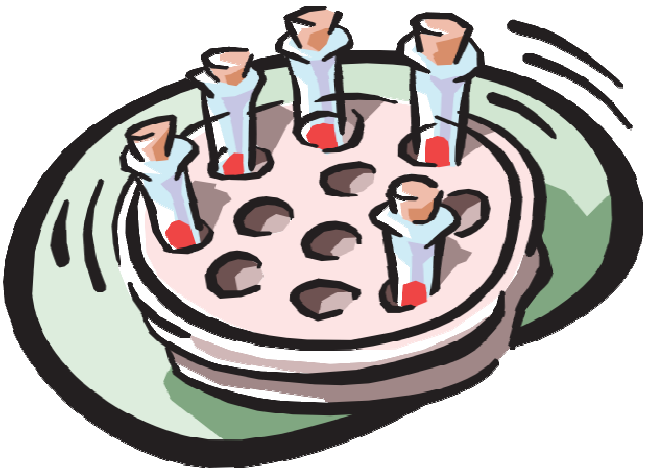
CLIA

CLINICAL LABORATORY IMPROVEMENT AMENDMENT



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DHSS Website: www.health.mo.gov **CMS Website**: www.cms.hhs.gov

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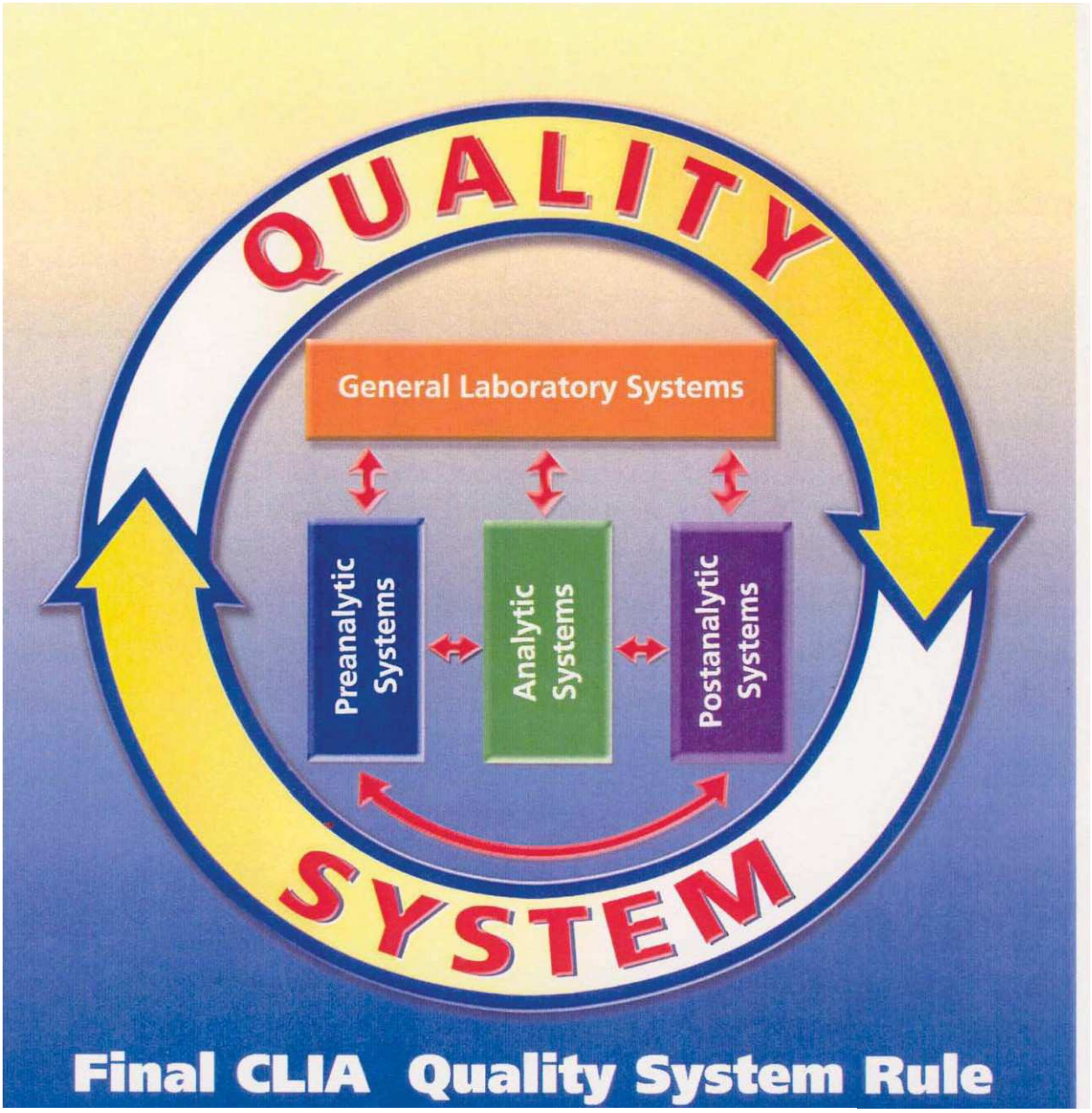
QUALITY
General Laboratory Systems
Preanalytic Systems
Analytic Systems
Postanalytic Systems
SYSTEM
Final CLIA Quality System Rule

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REQUIREMENT TO BE CERTIFIED

CLIA stipulates that no testing of a human specimen for health assessment purposes may be performed unless the testing facility has a current certificate. The requirement for certification may be found at http://www.cms.hhs.gov/clia/. Certificate applications may be found and printed from the Internet: http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf.

CERTIFICATE TYPES

1. Certificate of Waiver 493.15

Facilities performing only waived tests must apply for a certificate of waiver by completing and submitting a CMS Form 116. A certificate fee of $150.00 will be assessed after these forms are submitted. The certificate is good for two years.

Waived testing performed in any type of facility is waived from meeting operational and inspection requirements. Facilities holding a certificate of waiver will not be routinely inspected. Inspections will occur only as a result of substantial complaint OR to gather information.

A continuously updated list of waived tests can be found on the Internet at http://www.cms.hhs.gov/CLIA/downloads/CR5404.waivedtbl.pdf

2. Certificate of Provider-Performed Microscopy 493.19

Certain microscope tests performed by the physician or mid-level practitioner during the patient's visit may be certified under the PPM certificate. The certificate fee is $200.00, assessed after the application is processed, and good for two years.

A continuously updated list of PPMP tests can be found on the Internet at http://www.cms.hhs.gov/CLIA/downloads/ppmp.list.pdf

ALL OTHER TESTING MUST BE CERTIFIED WITH: CERTIFICATE OF COMPLIANCE OR CERTIFICATE OF ACCREDITATION

3. Certificate of Compliance

Non-waived and non-PPM testing that is not performed in an accredited laboratory must hold a certificate of compliance. Fees are assessed based on test volumes. Inspections are performed by the state agencies.

A continuously updated list of Compliance tests can be found on the Internet at http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf

4. Certificate of Accreditation

A laboratory may be voluntarily accredited by one of the approved, non-profit laboratory accreditation agencies. CLIA issues the certificate, but inspection and enforcement activities are carried out by the accreditation agency. CLIA assess certificate and nominal "validation" fees.

A continuously updated list of Accreditation tests can be found on the Internet at http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf

PROVIDER PERFORMED MICROSCOPY (PPM)
493.19

Requirements:

A. Testing must be personally performed by a qualified provider during the patient's visit on a specimen obtained from his or her own patient or a patient of a medical group of which the physician is a member.

B. The PPM certificate is limited to the following tests:

- Wet mounts – including vaginal, cervical or skin specimens
- KOH Preps
- Pinworm exams
- Fern test
- Post-coital exams
- Urine sediment exams
- Nasal smears for granulocytes
- Fecal leukocytes
- Qualitative semen
- All waived tests

Laboratories holding a PPM certificate are exempt from inspection but **are not exempt** from following the applicable CLIA regulations.

Apply for a PPM certificate by completing CMS Form 116.

REGULATED TEST SYSTEMS AND ANALYTES FOR PROFICIENCY TESTING PURPOSES

Microbiology

bacteriology: Gram Stains, rapid Strep test, culture, antibiotic susceptibility
mycobacteriology: acid-fast stain, culture, antibiotic susceptibility
mycology: culture
parasitology: detection, identification
virology: detection, identification

Diagnostic immunology

syphilis serology: all tests
general immunology: alpha-1 antitrypsin, alpha-fetoprotein, ANA, ASO, HIV, C3, C4, Hepatitis BsAg, anti-HBc, HBeAg, IgA, G, E, M, infectious mono, RA factor, rubella

Chemistry

routine chemistry: ALT/SGPT, albumin, alkaline phosphatase, amylase, AST/SGOT, bilirubin, blood gases, calcium, chloride, cholesterol, HDL, CPK and isoenzymes, creatinine, glucose, iron, LDH and isoenzymes, magnesium, potassium, sodium, total protein, triglycerides, urea nitrogen, uric acid.
endocrinology: cortisol, free thyroxin, HCG, T3 uptake, T3, TSH, T4
toxicology: blood alcohol, lead, carbamazepine, digoxin, ethosuximide, gentamycin, lithium, phenobarbitol, phenytoin, primidine, procainamide, quinidine, theophylline, tobramycin, valproic acid

Hematology (no subspecialties)

cell identification or differential, RBC, hematocrit, hemoglobin, WBC, platelet count, fibrinogen, PTT, PT

Pathology

histopathology: (no proficiency testing)
oral pathology: (no proficiency testing)
cytology: enrollment now required as of 6/30/05.

Immunohematology

ABO & Rh
unexpected antibody detection
compatibility testing
antibody identification

Radiobioassay (no proficiency testing)

Histocompatibility (no proficiency testing. A cell exchange program is required.)

Clinical Cytogenetics (no proficiency testing)

SUBPART J

Facility Administration
493.1100 – 493.1105

- Must have sufficient space and equipment.
- Must be in compliance with Federal, State, and Local Laws
- Records, slides, blocks, and tissues must be stored to ensure proper preservation
- Record retention: **all** records are to be retained for 2 years except for:

Immunohematology	5 years
Pathology	10 years
Blocks	2 years
Cytology slides	5 years

- If a laboratory ceases operation, the laboratory must retain records, slides, and blocks for the specified time frames
- Requirements for transfusion services

SUBPART K

Quality Systems for Non-waived Testing
493.1200 – 493.1299

Laboratories s must:

- Be inspected once every two years to assure compliance with operational regulations.
- Enroll and participate in an approved proficiency testing program for specialties and subspecialties if the laboratory performs tests that are regulated in those specialties and subspecialties (See page 3).
- Be subject to all enforcement and sanction (including proficiency testing sanction) regulations.
- Develop a written quality assessment program that includes general lab systems, pre-analytic, analytic, and post-analytic policies and procedures.
- Correcting problems causing unsuccessful performance in proficiency testing.
- Evaluating tests not covered in a proficiency testing program.
- Personnel assessment.

GENERAL LABORATORY SYSTEMS
493.1230

- The laboratory must ensure confidentiality of patient information through all phases of the testing process
- The laboratory must have policies and procedures that ensure the positive identification and optimum integrity of patient's specimens throughout the testing process.
- The laboratory must have a system to document all complaints and problems reported to the laboratory.
- The laboratory must have a system in place to identify and document problems in communications between the laboratory and the authorized person who orders or receives test results.
- The laboratory must establish and follow policies and procedures to assess the competency of the testing personnel.
- The laboratory must evaluate and document the evaluation of ungraded proficiency testing results
- At least twice annually, the laboratory must verify the accuracy of testing performed but not regulated by proficiency testing.
- **QUALITY ASSESSMENT FOR GENERAL LABORATORY SYSTEMS** QA includes assessing practices/issues related to patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency and proficiency testing performance. The laboratory must document the review of corrective actions to see if they are effective and discussed with appropriate personnel.

PRE-ANALYTIC SYSTEMS
493.1240

- The laboratory must have a written or electronic request for patient testing from an authorized person: can solicit electronic authorization within 30 days of an oral request.
- The test requisition must solicit the following:
  - Patient's name or unique identifier
  - Sex
  - Age or DOB
  - Tests to be performed
  - Source of specimen when appropriate
  - Date and time of specimen collection
  - Pap smears must solicit last menstrual period, and previous abnormal reports, treatment or biopsy.
  - Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation of results if applicable.
- The laboratory must maintain a system that provides for: proper patient preparation, proper specimen collection, identification, labeling, preservation, transportation, processing, and accurate result reporting. In addition, the laboratory must have available and follow written policies and procedures for this system.
- The laboratory must ensure that test requisition information entered into a record system or LIS is transcribed or entered accurately.
- The laboratory may refer a specimen for testing only to a CLIA certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.
- **QUALITY ASSESSMENT FOR PRE-ANALYTIC SYSTEM**
  QA includes assessing practices/issues related to test requests, specimen submission, handling and referral. The laboratory must document the review of corrective actions to see if they are effective and have been discussed with appropriate personnel.

ANALYTIC SYSTEMS
493.1250

- Throughout the analytic systems section the laboratory must perform and follow all manufacturer's package insert requirements, suggestions and recommendations as approved by FDA.
- The laboratory must have a procedure manual for the step-by-step performance of all tests performed. This is to include all steps in the pre-analytic, analytic, and post analytic phases of testing, literature references, and the laboratory's system for reporting results.
- Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.
- The laboratory must choose appropriate test systems, follow the manufacturer's instructions, and must not use reagents beyond their expiration date.
- For new, **unmodified**, FDA-cleared or approved test systems, introduced in the laboratory on or after 4/24/2003, the laboratory **MUST** verify the performance specifications established by the manufacturer in the laboratory's environment using the laboratory's testing personnel for the following: accuracy, precision, reportable range and verify that the manufacturer's reference ranges are appropriate for the laboratory's patient population.
- For new, **modified**, FDA-cleared or approved test systems, new test systems not subject to FDA clearance or approval and test systems that the manufacturer does not provide performance specifications, the laboratory **MUST** establish performance specifications for the following: accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference ranges, and any other performance characteristics required for test performance.
- The laboratory must document all of the verification and establishment activities.
- Establish an equipment function check and maintenance protocol and document all checks and maintenance performed.
- Perform and document calibration procedures.
- Perform and document calibration verification procedures using at least 3 or more levels, at a minimum of every 6 months for chemistry instruments.
- Two levels of controls each day of testing are required for automated hematology instruments to meet the calibration verification requirements.
- Quality control procedures: for each quantitative and qualitative procedure include two levels of control materials each testing day. No controls are required for urine microscopic examinations.
- **EXCEPTIONS**: If the laboratory chooses to reduce the frequency of control performance on non-waived analytes to less that the CLIA minimum of two levels each day of testing, the laboratory must perform adequate IQCP study **(pamphlet available).**

- Over time, rotate control material testing among all operators who perform the test.
- For quantitative procedures the laboratory must verify or establish the criteria for acceptability of all control materials.
- Check each batch, lot number, shipment of reagents, disks, stains, antisera, and identification systems for positive and negative reactivity.
- Each day of use (unless otherwise specified in the subpart), test-staining materials with a positive and negative control.

SPECIALTY and SUBSPECIALTY QC REQUIREMENTS

Routine Chemistry – 493.1267

- For **Blood Gas** analysis: must perform calibration or calibration verification in accordance with the manufacturer instructions if the meet or exceed the minimum control requirements found at **493.1255**. Must test one control each eight hours for Blood Gas analysis, the combination of high and low controls and calibrators used each day must check **normal, alkalosis and acidosis**. If the instrument does not internally verify the calibration every thirty (30) minutes, then a calibrator or external control must be run with **e ach** patient test event.

Hematology – 493.1269

- For manual cell counts using a hemocytometer, one level of control material must be tested every eight hours; and patient specimens and control materials must be tested in duplicate.
- For all non-manual coagulation test systems, the laboratory must include two levels of control material each eight hours of operation and each time a reagent is changed. Exceptions exist for coagulation testing performed on instruments eligible for EQC (ex: D-dimer). The laboratory must document the manual check of the INR calculation and each lot number with the ISI value provided by the manufacturer.
- For manual coagulation tests each person performing tests must perform two levels of control materials before testing patient samples, and each time a reagent is changed; the patient specimens and control specimens must be tested in duplicate.
- Automated hematology instruments require a minimum of two levels of control materials each **day** of testing.

COMPARISON OF TEST RESULTS 493.1281

- The laboratory must have a system that twice a year evaluates and defines the relationship between test results for same analyte using the different methodologies, instruments or testing sites.
- The laboratory must have written criteria for acceptable differences in the test values.
- The laboratory must have a written system to monitor and to identify and assess patient test results that appear inconsistent with the relevant criteria for patient age, sex, diagnosis or pertinent clinical data, distribution of test results, and relationship with other test parameters.
- The laboratory must document all test result comparison activities.

CORRECTIVE ACTIONS
493.1282

- If results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability, all patient test results obtained in the test runs since the last acceptable test run must be evaluated to determine if the patient test results have been adversely affected.
- The laboratory must perform and document corrective action necessary to ensure the reporting of accurate and reliable patient test results. The laboratory must perform and document corrective actions when the criteria for proper storage of reagents and specimens are not met.

TEST RECORDS
493.1283

- The laboratory must maintain an information or record system that includes:

    - Positive identification of the specimen.
    - The date and time of specimen receipt into the laboratory
    - The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.
    - The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).
    - Records of patient testing including, if applicable, instrument printouts, must be retained.

ANALYTIC SYSTEMS ASSESSMENT
493.1289

- The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in **493.1251 through 493.1283.**
- The analytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems assessment reviews with appropriate staff.
- The laboratory must document all analytic systems assessment activities.

POST ANALYTIC SYSTEMS
493.1290

- The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately sent from the point of data entry to final report destination.
- The test report must include:
    - Patient's name and ID **or** unique identifier and ID number.
    - Name and address of the laboratory performing the test.
    - Test report date.
    - Test performed.
    - Specimen source, when appropriate.
    - Test results.
- All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready ID and timely accessibility.
- **QUALITY ASSESSMENT FOR POST ANALYTIC SYSTEMS**
  QA must establish and follow written policies or procedures to monitor, assess, and correct problems, identified in the post analytic systems. The QA must include a review of the effectiveness of corrective actions taken, revision of policies and procedures necessary to prevent recurrence of problems and discussion of post analytic systems assessment reviews with appropriate staff.

SUBPART M

PERSONNEL
493.1403

Moderate Complexity Testing – Director
Technical Consultant
Clinical Consultant
Testing Personnel

High Complexity Testing – Director
Technical Supervisor
Clinical Consultant
General Supervisor
Cytology Supervisor
Testing Personnel
Cytotechnologist

DIRECTOR QUALIFICATIONS

Moderate Complexity Testing:

A. Missouri licensed physician AND
    1. Pathologist OR
    2. 1 year experience directing or supervising testing OR
    3. Lab training during residency
B. Doctoral degree AND
    1. Board certification by ABMM, ABCC, ABB, ABMLI, OR
C. Master's degree in a chemical physical, biological, or clinical laboratory science AND
   1 year training and 1 year supervisory experience
D. Bachelor's degree in a chemical physical, biological, or clinical laboratory science AND
   2 years' experience and 2 years supervisory experience
E. Previously qualified

High Complexity Testing:

A. Missouri licensed physician AND
    1. Pathologist OR
    2. 1 year lab training during residency OR
    3. 2 years' experience
B. Doctoral degree AND
    1. Board certification by ABMM, ABCC, ABB, ABMLI OR
C. Previously qualified

DIRECTOR RESPONSIBILITIES

Moderate AND **High Complexity Testing**

Each Director may be listed on no more than FIVE certificates including PPMP certificates.

The director must:

- Be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed.
- Monitor testing personnel to assure that they are competent.
- Specify in writing the responsibilities and duties of each consultant and supervisor as well as each person engaged in the testing process.

The director must ensure the following:

- All duties are properly performed.
- All test systems provide properly reported, accurate test results.
- The physical plant and environmental conditions are appropriate for testing and safe for employees.
- Laboratory personnel are performing tests in accordance with established procedures.
- The laboratory is enrolled in an approved proficiency testing program; that proficiency test results are reviewed with laboratory staff; and that corrective action is taken for unsatisfactory test results.
- Quality control and quality assurance programs are established.
- All remedial actions are taken and documented when problems are discovered, and that no patient tests are reported unless testing performance is assured to be in conformance with the laboratory's stated characteristics.
- Consultation is available on quality and interpretation of tests.
- Employment of sufficient number of properly qualified or trained testing personnel.
- An approved procedure manual is available.

QUALIFICATIONS

Technical Consultant (Moderate Complexity Testing) –

A. Missouri-licensed physician AND
   1. Pathologist OR
   2. 1 year experience in specialty or subspecialty

B. Doctoral or Master's degree in a chemical, physical, biological, or clinical laboratory science AND 1 year experience in specialty or subspecialty.

C. Bachelor's degree in a chemical physical, biological, or clinical laboratory science AND 2 years' experience in specialty or subspecialty.

Technical Supervisor (High Complexity Testing) –

A. All specialties except cytogenetics & histocompatibility
   Missouri-licensed, board certified pathologist.

B. Bacteriology, Mycology, Mycobacteriology, Parasitology, Virology, Immunology, Chemistry, Hematology, Radiobioassay
   1. Missouri-licensed physician or doctoral degree in a chemical physical, biological, or clinical laboratory science AND 1 year experience in the specialty or subspecialty.
   2. Master's degree in chemical, physical, biological, or clinical laboratory science AND 2 years' experience in the specialty that includes 6 months experience in the subspecialty.
   3. Bachelor's degree in chemical, physical, biological, or clinical laboratory science AND 4 years' experience in the specialty that includes 6 months experience in the subspecialty.

C. Immunohematology
   Missouri-licensed physician AND 1 year experience in high complexity immunohematology.

TECHNICAL CONSULTANT/SUPERVISOR RESPONSIBLITIES

The Technical Consultant/Supervisor must be accessible to the laboratory to provide consultation.

The Technical Consultant/Supervisor is responsible for the following:

- Selection of test methodology
- Verification of test procedure
- Enrollment of proficiency testing
- Establishing a quality control program and ensuring that it is carried out
- Resolving technical problems and ensuring that remedial actions are carried out
- Ensuring that patient test results are not reported until the test systems are functioning properly
- Identifying training needs
- Evaluating competency of testing personnel. Evaluation must include:
    1. Direct observation of routine testing
    2. Monitoring, recording and reporting of test results
    3. Reviewing worksheets, quality control records, proficiency testing, and preventive maintenance records
    4. Direct observation of instrument checks
    5. Assessment of test performance through previously analyzes samples, blind testing samples, or external proficiency testing
    6. Assessment of problem solving skills
- Evaluating and documenting performance of testing personnel at least semiannually during the first year that the person tests samples and annually thereafter.

CLINICAL CONSULTANT

(Mode rate & High Complexity Testing)

QUALIFICATIONS

Missouri-licensed physician or Doctoral degree in a chemical, physical, biological, or clinical laboratory science AND Board certification by AAMM, ABCC, ABB, or ABMLI.

RESPONSIBILITIES

- Be available to provide clinical consultation.
- Be available to assist laboratory's clients in proper ordering of tests.
- Ensure test reports include pertinent information.
- Ensure consultation is available to laboratory's clients.

GENERAL SUPERVISOR

(Needed for High Complexity Testing Only)

QUALIFICATIONS

1. Qualify as director or technical supervisor.
2. Missouri-licensed physician with 1 year experience in high complexity testing.
3. Earned Associate's degree in laboratory science or medical laboratory technology and 2 years' experience.
4. Previously qualified.
5. Grandfather.

RESPONSIBILITIES

1. Must be accessible.
2. Must provide day-to-day supervision.
3. Monitor analyses and examinations to assure acceptable levels of performance are maintained.

TESTING PERSONNEL

QUALIFICATIONS

Moderate Complexity Testing –

Minimum requirement: High school diploma or GED and documentation of training for testing before analyzing patient specimens.

High Complexity Testing –

Minimum requirement: Earned Associate's degree in laboratory science or medical laboratory technology. (Equivalency: 60 semester hours with adequate course break-down AND training or experience).

OR

Prior to April 24, 1995, have graduated from a medical laboratory school that has been approved or have completed a 50-week military training course. High school graduates with appropriate training who are performing high complexity testing on or before April 25, 1995, will continue to qualify.

RESPONSIBILITIES

- Perform only those tests authorized by the director
- Follow laboratory procedures
- Maintain records
- Adhere to laboratory's quality control policies, document all control activities, instrument and procedural calibrations and maintenance.
- Follow the laboratory's established corrective action policies and procedures
- Be capable of identifying problems that may affect results
- Document all corrective action

SUBPART Q

INSPECTIONS
493.1771

1. Inspections will be announced.

2. Laboratories may be required to:
   a) test samples during the inspection and be observed
   b) allow all employees to be interviewed
   c) permit access to all areas of the facility
   d) provide copies of all records and data

3. The lab must have all records and data accessible and retrievable within a reasonable time frame during the course of an inspection.

4. Laboratories may be re-inspected at any time necessary to evaluate the laboratory's ability to provide accurate and reliable test results.

5. Failure to submit to an inspection will result in suspension or termination of Medicare/Medicaid payments to the laboratory, and suspension or revocation of the CLIA certificate.

ACCEPTABLE PLANS OF CORRECTION

The Plan must state:

- How the deficient practice will be corrected or how it was corrected;
- What corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and
- Who will monitor the corrective action to ensure the deficient practice does not recur.
- Condition Levels Deficiencies
  - Requires an Allegation of Compliance: must include Plan of Correction (POC) with documentation showing evidence that the Condition Level Deficiencies have been corrected.

NOTIFICATION REQUIREMENTS
493.51

A laboratory with a currently valid CLIA certificate must notify the CLIA Program (address on cover page) by letter within 30 days if any changes occur in:

- Ownership (including Federal Tax ID number)
- Location
- Director
- Name
- Technical Supervisor (High Complexity Testing)
- Change in certificate type (Changing to a Certificate of Compliance or Accreditation will require a new 116 to be filled out)

INITIAL/RENEWAL CHECKS
(After you receive a User Fee Coupon from Portland, OR)

The *User Fee Coupon* will offer the option to pay the fee on-line at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA, or pay by check. Make checks payable to: CLIA Laboratory Program, write the CLIA number on the check and send the check and coupon to the address below:

CMS Laboratory Program
PO Box 3056
Portland, OR 97208-3056

Send any changes regarding the certificate information to:

DHSS
CLIA Program
P.O. Box 570
Jefferson City, MO 65102

You may fax the changes to (573) 751-6158 or email to CLIA@health.mo.gov. You may also submit any changes to the state agency by using the area provided on the back of your coupon.

Changes would include:

- Name of facility
- Phone/fax numbers
- Federal Tax ID number
- Director
- Location

GUIDELINES FOR COUNTING TEST

- For histocompatibility, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA cross match is counted as 1 test.
- For microbiology, susceptibility testing is counted as 1 test per group of antibiotics used to determine sensitivity for 1 organism. Cultures are counted as 1 per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- Testing for allergens should be counted as 1 test per individual allergen.
- For chemistry profiles, each individual analyte is counted separately.
- For urinalysis, microscopic and non-waived macroscopic (dipstick) examinations, each counts as 1 test. Waived dipsticks are not counted.
- For complete blood counts, each measured individual analyte that is ordered and reported is counted separately. Differentials are counted as 1 test.
- Do not count calculations (i.e., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency test assays.
- For immunohematology, each ABO, Rh, antibody screen, cross match or antibody identification is counted as 1 test.
- For histopathology, each block (not slide) is counted as 1 test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For cytology, each slide (not case) is counted as 1 test for both Pap smears and non-gynecologic cytology.
- For cytogenetics, the number of tests is determined by the number of specimen types processed on each patient, i.e., a bone marrow and a venous blood specimen received on 1 patient is counted as 2 tests.

INTERNET SITES

GOVERNMENT

List of CLIA approved Tests, specialty grouping and complexity--
http://www.cms.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage
National Laboratory Training Network .....http://www.phppo.cdc.gov/nltn/default.aspx
Dept. of Health & Human Services.....http://www.os.dhhs.gov/
Center for Disease Control & Prevention .....www.cdc.gov
Clinical Laboratory Improvement Amendments.....http://www.cms.gov/clia/
Interpretive Guidelines--
http://www.cms.gov/CLIA/03_Interpretive_Guide lines_for_Laboratories.asp#TopOfPage

PRIVATE

American Assn. for Clinical Chemistry ..... http://www.aacc.org/AACC/
American Assn for Bioanalysts.....www.aab.org
American Assn of Blood Banks.....www.aabb.org
American Assn of Family Physicians .....http://www.aafp.org/online/en/home.html
American Assn of Health Plans.....www.aahp.org
America's Blood Centers.....www.americasblood.org
American Hospital Association..... www.aha.org
American Medical Technologists www.amt1.com
American Society for Clinical Laboratory Science..... www.ascls.org
American Society for Microbiology .....www.asm.org
American Society for Clinical Pathologists .....www.ascp.org
College of American Pathologists..... www.cap.org
Clinical Laboratory Management Association.....www.clma.org
COLA (Commission of Laboratory Accreditation) .....www.cola.org
Joint Commission on Healthcare Accreditation..... http://www.jointcommission.org/
National Association for Accreditation of Clinical Lab Scientists..... www.naacls.org
Clinical & Lab Standards Institute..... www.nccls.org